RANDOX

PRODUCT INFORMATION

PS2683

585LPC

Please note that while Antithrombin III is present in PS2683 - Liquid Assayed Specific Protein Control Level 2 - lot 585LPC, targets and ranges are not available for this analyte.

CCS6790

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 2 (SP CONTROL 2)

CAT. NO. PS2683
SIZE: 3 x 1ml
GTIN: 05055273204902

LOT NO. 585LPC
EXPIRY: 2023-06-28

INTENDED USE
This product is intended for *in vitro* diagnostic use, in the quality control of serum on clinical chemistry and immunoassay systems. The Assayed Liquid Protein Controls are for the control of accuracy.

DEVICE DESCRIPTION
The Liquid Protein Controls are supplied at 3 levels, level 1, 2 and 3. Target values and ranges are supplied for the analytes listed in the values table. Note: Free Lambda light chains are not for use in the U.S.

SAFETY PRECAUTIONS AND WARNINGS
For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Human source material, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.
However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Health and Safety Data Sheets are available on request.

STORAGE AND STABILITY
OPENED: Store refrigerated (+2°C to +8°C). Protein control material is stable for 30 days at +2 to +8°C, if kept capped in original container and free from contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

UNOPENED: Store refrigerated (+2°C to +8°C). Stable to expiration date printed on individual vials.

Note: Free Kappa Light Chains is present in the Liquid Assayed Specific Protein Control material, but no claim is made for the expected value or stability of this analyte.

PREPARATION
The Liquid Protein Controls are supplied ready for use.

MATERIALS PROVIDED
Liquid Protein Control - Level 2 3 x 1 ml

MATERIALS REQUIRED BUT NOT PROVIDED
Not applicable.

LIMITATIONS
RF: Please note that the dilution of multi-controls on certain systems can result in the over recovery of R.F. compared to the undiluted control. This is due to complex Immunoglobulin interactions.

ASSIGNED VALUES
Each batch of Protein Control is submitted to approximately 100 laboratories and values are assigned from a consensus of results obtained by these laboratories. With each batch, a control range is provided for individual parameters and each parameter method.

If a method is unavailable, contact Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 94451070 or email Technical.Services@randox.com.

EC REP Randox Teoranta, Meenmore,
Dungloe, Donegal,
F94 TV06, Ireland

Rev. 18 Nov '22 me

RANDOX

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 2 (SP CONTROL 2)

Cat. No. PS2683 Lot No. 585LPC Size: 3 x 1 ml Expiry: 2023-06-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Albumin	g/l	44.1	37.5	50.7	Bromocresol Green (IFCC Cal.)
	g/dl	4.41	3.75	5.07	
	g/l	43.7	37.1	50.3	Bromocresol Purple (IFCC Cal.)
	g/dl	4.37	3.71	5.03	
	g/l	43.6	37.1	50.1	Nephelometric (IFCC Cal.)
	g/dl	4.36	3.71	5.01	
	g/l	45.4	38.6	52.2	Bromocresol Green (Non IFCC Cal.)
	g/dl	4.54	3.86	5.22	
	g/l	45.0	38.3	51.8	Turbidimetric Assays (IFCC Cal.)
	g/dl	4.50	3.83	5.17	
Alpha-1-Acid Glycoprotein	g/l	0.965	0.772	1.16	Turbidimetric (IFCC Cal.)
	mg/dl	96.5	77.2	116	
	g/l	1.04	0.832	1.25	Nephelometric (IFCC Cal.)
	mg/dl	104	83.2	125	
	g/l	0.963	0.770	1.16	Turbidimetric (Non IFCC Cal.)
	mg/dl	96.3	77.0	116	
Alpha-1-Antitrypsin	g/l	1.32	1.06	1.58	Turbidimetric (IFCC Cal.)
	mg/dl	132	106	158	
	g/l	1.43	1.14	1.72	Nephelometric (IFCC Cal.)
	mg/dl	143	114	172	
	g/l	1.32	1.06	1.58	Turbidimetric (Non IFCC Cal.)
	mg/dl	132	106	158	
Alpha-2-Macroglobulin	g/l	2.06	1.65	2.47	Nephelometric (IFCC Cal.)
	mg/dl	206	165	247	
Alpha-fetoprotein	KIU/l = IU/ml	29.0	23.2	34.8	Chemiluminescence (IFCC Cal.)
	ng/ml	35.1	28.1	42.1	
	KIU/l = IU/ml	29.1	23.3	34.9	Chemiluminescence (Non IFCC Cal.)
	ng/ml	35.2	28.2	42.2	
Anti Streptolysin O	IU/ml	224	179	269	Turbidimetric (IFCC Cal.)
	IU/ml	231	185	277	Turbidimetric (Non IFCC Cal.)
	IU/ml	138	110	166	Neph. Beckman (IFCC Cal.)
	IU/ml	231	185	277	Siemens Nephelometric (IFCC Cal.)
	IU/ml	234	187	281	Siemens Nephelometric (Non IFCC Cal.)
Beta-2-microglobulin	µg/ml = mg/l	3.00	2.40	3.60	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	2.99	2.39	3.59	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	3.53	2.82	4.24	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	3.48	2.78	4.18	Turbidimetric (Non IFCC Cal.)
C-Reactive Protein	mg/l	38.8	31.0	46.6	Vitros (IFCC Cal.)
	mg/l	48.8	39.0	58.6	Turbidimetric (IFCC Cal.)
	mg/l	46.9	37.5	56.3	Nephelometric (IFCC Cal.)
	mg/l	39.8	31.8	47.8	Vitros (Non IFCC Cal.)
	mg/l	48.4	38.7	58.1	Turbidimetric (Non IFCC Cal.)

RANDOX

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 2 (SP CONTROL 2)

Cat. No. PS2683 Lot No. 585LPC Size: 3 x 1 ml Expiry: 2023-06-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
C-Reactive Protein	mg/l	51.0	40.8	61.2	Beckman Turb Latex (IFCC Cal)
Caeruloplasmin	g/l	0.393	0.295	0.491	Nephelometric (IFCC Cal.)
	mg/dl	39.3	29.5	49.1	
	g/l	0.347	0.260	0.434	Turbidimetric (IFCC Cal.)
	mg/dl	34.7	26.0	43.4	
	g/l	0.387	0.290	0.484	Nephelometric (Non IFCC Cal.)
	mg/dl	38.7	29.0	48.4	
	g/l	0.305	0.229	0.381	Turbidimetric (Non IFCC Cal.)
	mg/dl	30.5	22.9	38.1	
Complement C3	g/l	1.69	1.35	2.03	Turbidimetric (IFCC Cal.)
	mg/dl	169	135	203	
	g/l	1.68	1.34	2.02	Nephelometric (IFCC Cal.)
	mg/dl	168	134	202	
	g/l	1.75	1.40	2.10	Nephelometric (Non IFCC Cal.)
	mg/dl	175	140	210	
	g/l	1.73	1.38	2.08	Turbidimetric (Non IFCC Cal.)
	mg/dl	173	138	208	
	g/l	1.69	1.35	2.03	Vitros 5.1 FS microtip assay
	mg/dl	169	135	203	
Complement C4	g/l	0.285	0.228	0.342	Turbidimetric (IFCC Cal.)
	mg/dl	28.5	22.8	34.2	
	g/l	0.303	0.242	0.364	Nephelometric (IFCC Cal.)
	mg/dl	30.3	24.2	36.4	
	g/l	0.300	0.240	0.360	Nephelometric (Non IFCC Cal.)
	mg/dl	30.0	24.0	36.0	
	g/l	0.271	0.217	0.325	Turbidimetric (Non IFCC Cal.)
	mg/dl	27.1	21.7	32.5	
	g/l	0.299	0.239	0.359	Vitros 5.1 FS microtip assay
	mg/dl	29.9	23.9	35.9	
Ferritin	ng/ml = µg/l	177	142	212	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	179	143	215	Turbidimetric (Non IFCC Cal.)
	ng/ml = µg/l	218	174	262	Chemiluminescence (IFCC Cal.)
	ng/ml = µg/l	237	190	284	Chemiluminescence (Non IFCC Cal.)
Free Lambda Light Chains	mg/L	13.6	10.9	16.3	Nephelometric - Binding Site
	mg/L	14.0	11.2	16.8	Nephelometric - Siemens
	mg/L	11.6	9.28	13.9	Turbidimetric
Haptoglobin	g/l	1.05	0.840	1.26	Nephelometric (IFCC Cal.)
	mg/dl	105	84.0	126	
	g/l	1.05	0.840	1.26	Turbidimetric (IFCC Cal.)
	mg/dl	105	84.0	126	
	g/l	1.06	0.848	1.27	Turbidimetric (Non IFCC Cal.)
	mg/dl	106	84.8	127	
Immunoglobulin A	g/l	2.99	2.24	3.74	Turbidimetric (IFCC Cal.)
	mg/dl	299	224	374	
	g/l	3.16	2.37	3.95	Nephelometric (IFCC Cal.)
	mg/dl	316	237	395	

RANDOX

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 2 (SP CONTROL 2)

Cat. No. PS2683 Lot No. 585LPC Size: 3 x 1 ml Expiry: 2023-06-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Immunoglobulin A	g/l	3.15	2.36	3.94	Nephelometric (Non IFCC Cal.)
	mg/dl	315	236	394	
	g/l	3.05	2.29	3.81	Turbidimetric (Non IFCC Cal.)
	mg/dl	305	229	381	
	g/l	3.18	2.39	3.98	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	318	239	397	
Immunoglobulin E	KIU/l = IU/ml	174	139	209	Fluorimetric (Non IFCC Cal.)
	KIU/l = IU/ml	169	135	203	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	155	124	186	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	144	115	173	Turbidimetric (Non IFCC Cal.)
Immunoglobulin G	g/l	15.5	12.7	18.3	Turbidimetric (IFCC Cal.)
	mg/dl	1550	1270	1830	
	g/l	15.6	12.8	18.4	Nephelometric (IFCC Cal.)
	mg/dl	1560	1280	1840	
	g/l	15.2	12.5	17.9	Nephelometric (Non IFCC Cal.)
	mg/dl	1520	1250	1790	
	g/l	15.6	12.8	18.4	Turbidimetric (Non IFCC Cal.)
	mg/dl	1560	1280	1840	
	g/l	16.7	13.7	19.7	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	1670	1370	1970	
Immunoglobulin M	g/l	1.19	0.952	1.43	Turbidimetric (IFCC Cal.)
	mg/dl	119	95.2	143	
	g/l	1.26	1.01	1.51	Nephelometric (IFCC Cal.)
	mg/dl	126	101	151	
	g/l	1.29	1.03	1.55	Nephelometric (Non IFCC Cal.)
	mg/dl	129	103	155	
	g/l	1.18	0.944	1.42	Turbidimetric (Non IFCC Cal.)
	mg/dl	118	94.4	142	
	g/l	1.20	0.960	1.44	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	120	96.0	144	
Kappa Light Chain	g/l	12.7	10.2	15.2	Nephelometric - Beckman
	mg/dl	1270	1020	1520	
	g/l	3.67	2.94	4.40	Nephelometric - Siemens
	mg/dl	367	294	440	
	g/l	3.83	3.06	4.60	Turbidimetric
	mg/dl	383	306	460	
Lambda Light Chain	g/l	7.02	5.62	8.42	Nephelometric - Beckman
	mg/dl	702	562	842	
	g/l	2.04	1.63	2.45	Nephelometric - Siemens
	mg/dl	204	163	245	
	g/l	2.12	1.70	2.54	Turbidimetric
	mg/dl	212	170	254	
Prealbumin	g/l	0.276	0.221	0.331	Nephelometric (IFCC Cal.)
	mg/dl	27.6	22.1	33.1	
	g/l	0.268	0.214	0.322	Turbidimetric (IFCC Cal.)
	mg/dl	26.8	21.4	32.2	

RANDOX

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 2 (SP CONTROL 2)

Cat. No. PS2683 Lot. No. 585LPC Size 3 x 1ml Expiry 2023-06-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Prealbumin	g/l	0.272	0.218	0.326	Turbidimetric (Non IFCC Cal.)
	mg/dl	27.2	21.8	32.6	
Protein Total	g/l	70.0	56.0	84.0	Biuret reaction end point
	g/dl	7.00	5.60	8.40	
Retinol Binding Protein	mg/l	42.5	34.0	51.0	Nephelometric (Non IFCC Cal.)
Rheumatoid Factor	U/ml	29.5	22.1	36.9	Turbidimetric (Non IFCC Cal.)
	U/ml	26.2	19.7	32.8	Siemens Nephelometric (Non IFCC Cal.)
Transferrin	g/l	3.12	2.50	3.74	Turbidimetric (IFCC Cal.)
	mg/dl	312	250	374	
	g/l	3.15	2.52	3.78	Turbidimetric (Non IFCC Cal.)
	mg/dl	315	252	378	
	g/l	3.01	2.41	3.61	Nephelometric (IFCC Cal.)
	mg/dl	301	241	361	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com